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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/535,336	01/06/2006	Kazuhiro Ono	P27943	3742
7055 7590 10/30/2008 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER				
ROBERTS, LEZAH				
ART UNIT		PAPER NUMBER		
1612				
NOTIFICATION DATE		DELIVERY MODE		
10/30/2008		ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/535,336

Applicant(s)

ONO ET AL

Examiner

LEZAH W. ROBERTS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/CDC)
- 4) ☐ Interview Summary (PTO-413)
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____
- Paper No(s)/Mail Date _____

DETAILED ACTION

This Office Action is in response to the Amendment filed August 7, 2008. All previous rejections have been withdrawn unless stated below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is NON-FINAL.

Information Disclosure Statement

The IDS filed August 7, 2008 has not been considered because all the disclosed references have already been considered. See IDS mailed July 9, 2007 and February 27, 2008.

Claims

Claim Rejections - 35 USC § 112 – Written Description (New Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claims recite “an aqueous solution of *Perilla frutesen* var. *crispa* including polyphenol”.

The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See, e.g., *In re Wilder*, 22 USPQ 369, 372-3 (Fed. Cir. 1984). (Holding that a claim was not adequately described because the specification did ‘little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.’)

Mere indistinct terms (such as “an aqueous solution of *Perilla frutesen* var. *crispa* including polyphenol” used herein), however, may not suffice to meet the written description requirement. This is particularly true when a compound is claimed in purely functional terms. See *Univ. of Rochester v. G.D. Searle*, 69 USPQ2d 1886 (CAFC 2004) at 1892, stating:

The appearance of mere indistinct words in a specification or a claim, even an original claim, does not necessarily satisfy that requirement. A description of an anti-inflammatory steroid, i.e., a steroid (a generic structural term) described even in terms of its functioning of lessening inflammation of tissues fails to distinguish any steroid from others having the same activity or function. A description of what a material does, rather than of what it is, usually does not suffice.... The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. (Emphasis added).

Conversely, a description of a chemical genus will usually comprise a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See *Univ. of Cal. V. Eli Lilly*, 43 USPQ 2d 1398, 1406 (Fed. Cir. 1997). This is analogous to enablement of a genus under Section 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

A chemical genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. *If the genus has substantial variance, the disclosure must describe a sufficient number of species to reflect the variation within that genus.* See MPEP 2163. The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any *combination of such identifying characteristics that distinguish the claimed invention from other materials* and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. MPEP 2163.

Here, the specification does not provide a reasonably representative disclosure of useful polyphenols that may be isolated from *Perilla frutesen* var. *crispa*. Specifically, the specification discloses only that the polyphenol is from *Perilla frutesen* var. *crispa*, and this recitation is not viewed as being reasonably representative of the genus in its claimed scope because no readily apparent combination of identifying characteristics is provided, other than the disclosure of those specific species as examples of the claimed genus. The specification also does not disclose how to isolate suitable polyphenols that would perform the function of an anti-tartar agent, or the type of extract, such as a 70 ethanolic extract, that would yield the desired polyphenol or polyphenols that would possess the anti-tartar function.

Claim Rejections - 35 USC § 112 – Indefiniteness (New Rejection)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 3-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation "an aqueous solution of *Perilla frutesen* var. *crispa* including polyphenol". It cannot be determined from the claims whether this refers to an aqueous solution with *Perilla frutesen* var. *crispa*, which would inherently comprise a polyphenol, or a polyphenol isolated from *Perilla frutesen* var. *crispa*.

Claim Rejections - 35 USC § 103 – Obviousness (Previous Rejection)

Claims 1 and 3-5 were rejected under 35 U.S.C. 103(a) as being unpatentable over in Melman (US 2002/0156130) in view of Oriza (JP 2000-239136). The rejection is maintained. The rejection is withdrawn in regards to claim 3.

Applicant's Arguments

Applicant argues that the Declaration establishes a combination of polyphenol and glycolic acid achieves unexpected advantages. When a combination of polyphenol

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and glycolic acid are utilized in combination, there is obtained a more rapid dissolving of the dental calculus.

Examiner's Response

The Examiner has reconsidered the Declaration filed and there appears to be unexpected results when a specific extract or solution *Perilla frutesen var. crispa* polyphenol is in combination with glycolic acid. Although this appears to be the case, the claims are not commensurate in scope with the compositions of the Declaration insofar as the claims read on any polyphenol from *Perilla frutesen var. crispa* and the Declaration discloses specific extract.

Declaration

The declaration provides an Example wherein the *Perilla frutesen var. crispa* polyphenol was in the form of a 5% aqueous solution and produced by Meiji Seika Kaisha, Ltd. One milliliter of a 10% glycolic acid and 5% polyphenol was used and showed an increase in the weight of dental calculus dissolved that was more than the sum of calculus dissolved when using a glycolic acid and a 5% polyphenol solution separately in the same concentrations.

Examiner's Response to the Declaration

As stated above there appears to be unexpected results yet the claims are not commensurate in scope with the unexpected results. The claims read on *Perilla*

frutesen var. crispa that comprises polyphenols in water and not an aqueous extract of *Perilla frutesen var. crispa* comprising polyphenols as in the case of the Declaration. Furthermore, the claims are unclear insofar as it is not certain what is meant by "an aqueous solution of *Perilla frutesen var. crispa* including polyphenol". It is difficult to ascertain whether this refers to a solution comprising *Perilla frutesen var. crispa* that naturally contains a polyphenol or if the claims refers to specific polyphenol that is obtained from *Perilla frutesen var. crispa*. If the latter is the case, Applicant has not disclosed any characteristics of the polyphenol or how it is isolated from *Perilla frutesen var. crispa*. Therefore one of skill in the art would not be able to ascertain which polyphenol of *Perilla frutesen var. crispa* is suitable for the instant method. In regards to glycolic acid, the claims only recite an amount in regards to *Perilla frutesen var. crispa* and not glycolic acid. The claims encompass any amount of glycolic acid. Therefore the instant claims are not commensurate in scope with the Declaration and the rejection is maintained.

Claim Rejections - 35 USC § 103 – Obviousness (New Rejection)

Claims 3, 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Melman (US 2002/0156130) in view of Oriza (JP 2000-239136) as applied to claims 1 and 4 and 5, in further view of Zhu (WO 01/17494) and Tagashira et al. (JP409295944).

Melman discloses oral compositions comprising acid such as acetic acid. Acetic acid may be substituted or used in conjunction with other acids such as citric acid, lactic acid, glycolic acid and stearic acid (paragraph 0017). The acid reduces the growth of plaque bacteria. It is also used with other dental ingredients to treat the oral cavity. The pH of the compositions preferably ranges from 4 to 7. The compositions comprise chelating agents to dissolve calculus on the teeth. The compositions also comprise sodium chloride (Example 7). The compositions may also comprise antibacterial agents (paragraph 0041). The reference differs from the instant claims insofar as it does not disclose using polyphenols in the compositions.

Oriza discloses oral compositions comprising polyphenols from *Perilla frutescens* (see Abstract). The polyphenols act as an anti-bacterial to treat caries and periodontal disease. The reference differs from the instant claims insofar as it does not disclose the compositions comprise glycolic acid.

Zhu discloses oral compositions comprising polyphenols. The polyphenols are useful for their anti-caries, anti-gingivitis and effect against dental calculus. The compositions also comprise a buffering agent such as citric acid (page 9, lines 1-3). Enzymes may be incorporated into the compositions such as papain, dextranase and mutanase (page 18, lines 15-16), encompassing claims 6-7. The reference differs from the instant claims insofar as it does not disclose the compositions comprise glycolic acid or an aqueous solution of *Perilla frutescens* var. *crispa* including polyphenol.

Tagashira et al. disclose compositions comprising a polyphenol from hop bract. The compositions act as an anti-cariogenic composition. It prevents adhesion of glucan

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and microorganisms of decayed tooth to the surface of a tooth. The compositions also comprise surfactant (see Abstract), encompassing claim 8. The reference differs from the instant claims insofar as it does not disclose the compositions comprise glycolic acid or an aqueous solution of *Perilla frutescens* var. *crispa* including polyphenol.

It is *prima facie* obviousness to select a known material based on its suitability for its intended use. Also, established precedent holds that it is generally obvious to add known ingredients to known compositions with the expectation of obtaining their known function. See MPEP 2144.07. It would have been obvious to one of ordinary skill in the art to have added an enzyme or additional polyphenol to the compositions of the combined teachings of Melman and Oriza motivated by the desire to add the compound for its desired function, such as inhibiting adhesion of glucan and microorganisms of decayed tooth to the surface of a tooth and for its anti-calculus function, as disclosed by Zhu and Tagashira.

Claims 1 and 3-7 are rejected.

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to LEZAH W. ROBERTS whose telephone number is (571)272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick F. Krass can be reached on 571-272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Lezah W Roberts/
Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612